Advancing Transfusion and
Cellular Therapies Worldwide

April 06, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE Docket 2007D-0021, 28 February 2007, "Guidance for Industry Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members"

Dear FDA Dockets Manager:

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, developing and delivering programs and services to optimize patient and donor care and safety.

AABB reviewed the draft guidance document, *"Guidance for Industry Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members"*, and identified an area of great concern which warrants comment.

According to Section III, Making Briefing Materials Available to the Public, section B, Timeline for Submitting and Making Briefing Materials Publicly Available; "…we intend to post a publicly available version of the briefing materials on our Web site at least two full business days before the advisory committee meeting is scheduled to occur. With respect to meetings for which the briefing materials do not contain information that, under certain circumstances, could be considered exempt from public disclosure under FOIA, we will probably make the briefing materials available on our Web site more than two full business days before the advisory committee meeting is scheduled to occur." While this policy may be appropriate for meetings that debate the approval of one company's product, the Blood Product Advisory Committee (BPAC) typically discusses policy that will affect all blood collection facilities in the US. It is critical to gather information about the impact on operations, as well as the science that is the underpinning of any decision. It is for these reasons that the release of the meeting information so close to the meeting date is not acceptable.

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In order to adequately review, analyze and convene experts to discuss an appropriate position, AABB must be afforded ample time. Forty-eight hours does not provide enough time to accomplish this. AABB strongly encourages the FDA to provide a minimum of four weeks advance notification of meetings and agenda topics. A greater advance notice will allow individuals and organizations to prepare to participate. In conjunction with the greater advance notice, we recommend that advisory committee meeting materials be posted far enough in advance to enable us to accomplish these activities. It is frequently difficult to decipher the important aspects of the topics based solely on the title of the subject matter that is listed on agendas. It is particularly important to understand the questions that will be posed to the committee members, so that we can provide specific insight from the blood banking community. In addition, we recommend that additional information and/or a more explanatory topic title be listed on the agendas. The lack of sufficient information hinders our ability to provide accurate and substantial comments at the meeting.

AABB makes this recommendation acknowledging that there will be times when less than four weeks notification will be given due to the need to address unanticipated urgent events that arise.

AABB strongly supports initiatives that improve the safety of blood donors and transfusion recipients and stands ready to interact with the FDA as necessary.

Questions concerning these comments may be directed to Joseph L. Giglio, Deputy Director, Regulatory Affairs, AABB jgiglio@aabb.org

Sincerely,

Allene Carr-Greer, MT(ASCP)SBB
Director, Regulatory Affairs